

§ 71.22

packing requirements for such color additives deemed necessary to assure the safety of such use).

(2) Such regulations shall list the color additive only for the use or uses for which it has been found suitable and for which it may safely be employed. Alternatively, the Commissioner shall by order deny the petition, and notify the petitioner of such order and the reasons therefor.

(3) The regulation shall list any use or uses in meat, meat food product, or poultry product subject to the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) or the Poultry Products Inspection (PPIA) (21 U.S.C. 451 *et seq.*) for which the color additive has been found suitable and for which it may safely be employed.

(b) Whenever the Commissioner finds that batch certification is not necessary for the protection of the public health he will, by order, exempt the color additive from the certification procedure. In determining whether certification of a color additive is necessary, the Commissioner will consider the composition of the additive, its manufacturing process, possible impurities, its toxic potential, control and analytical procedures necessary to assure compliance with the listing specifications, and the variability of its composition.

[42 FR 15639, Mar. 22, 1977, as amended at 65 FR 51762, Aug. 25, 2000]

§ 71.22 Deception as a basis for refusing to issue regulations; deceptive use of a color additive for which a regulation has issued.

The Commissioner shall refuse to issue a regulation listing a color additive, if in his judgment the data before him show that such proposed use would promote deception of the consumer or would result in misbranding or adulteration within the meaning of the act. Such a finding shall be by order published in the FEDERAL REGISTER subject to the filing of objections and a request for a hearing by adversely affected parties. The issuance of a regulation for a color additive authorizing its use generally in or on a food, drug, or cosmetic shall not be construed as authorization to use the color additive in a manner that may promote decep-

21 CFR Ch. I (4–1–12 Edition)

tion or conceal damage or inferiority. The use of a color additive to promote deception or conceal damage or inferiority shall be considered as the use of a color additive for which no regulation has issued pursuant to section 721(b) of the act, even though the regulation is effective for other uses.

§ 71.25 Condition for certification.

(a) When the Commissioner cannot conclude from the information before him that there is a basis for exempting a color additive from the requirement of batch certification, he will so order by appropriate listing in part 74 of this chapter. The Commissioner's order shall state in detail the specifications that shall be met by the color additive.

(b) Each order shall state a period of time after which use of a color additive subject to batch certification but not from a batch certified by procedure prescribed in this section would result in adulteration of the product in which it is used.

§ 71.26 Revocation of exemption from certification.

If information becomes available to the Commissioner that a color additive that has been granted exemption from certification should not, for the protection of the public health, be so exempted, such exemption will be canceled by a notice published in the FEDERAL REGISTER.

§ 71.27 Listing and exemption from certification on the Commissioner's initiative.

Where a petition for a regulation to list a color additive has not been received and the Commissioner has available facts which demonstrate that a color additive should be listed and/or that certification procedure is not necessary in order to protect the public health, he may list such color additive by appropriate regulation and listing in part 73 or 74 of this chapter.

§ 71.30 Procedure for filing objections to regulations.

(a) Objections and hearings relating to color additive regulations under section 721 (b) and (c) of the act shall be governed by parts 10, 12, 13, 14, 15, 16, and 19 of this chapter.

(b) The fees specified in § 70.19 of this chapter shall be applicable.

§ 71.37 Exemption of color additives for investigational use.

(a) A shipment or other delivery of a color additive or of a food, drug, or cosmetic containing such a color additive for investigational use by experts qualified to determine safety shall be exempt from the requirements of section 402(c), 501(a), or 601(e) of the act, provided that the color additive or the food, drug, or cosmetic containing the color additive bears a label which states prominently, "Caution—Contains new color additive—For investigational use only." No animals used in such investigations, or their products, such as milk or eggs, shall be used for food purposes, unless the sponsor or the investigator has submitted to the Commissioner data demonstrating that such use will be consistent with the public health, and the Commissioner, proceeding as he would in a matter involving section 409(i) of the act, has notified the sponsor or investigator that the proposed disposition for food is authorized. Any person who contests a refusal to grant such authorization shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

(b) The person who introduced such shipment or who delivers the color additive or a food, drug, or cosmetic containing such an additive into interstate commerce shall maintain adequate records showing the name and post-office address of the expert to whom the color additive is shipped, date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment and delivery. Upon the request of a properly authorized employee of the Department, at reasonable times, he shall make such records available for inspection and copying.

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

Subpart A—Foods

- Sec.
- 73.1 Diluents in color additive mixtures for food use exempt from certification.
- 73.30 Annatto extract.
- 73.35 Astaxanthin.
- 73.37 Astaxanthin dimethyldisuccinate.
- 73.40 Dehydrated beets (beet powder).
- 73.50 Ultramarine blue.
- 73.75 Canthaxanthin.
- 73.85 Caramel.
- 73.90 β -Apo-8'-carotenal.
- 73.95 β -Carotene.
- 73.100 Cochineal extract; carmine.
- 73.125 Sodium copper chlorophyllin.
- 73.140 Toasted partially defatted cooked cottonseed flour.
- 73.160 Ferrous gluconate.
- 73.165 Ferrous lactate.
- 73.169 Grape color extract.
- 73.170 Grape skin extract (enocianina).
- 73.185 Haematococcus algae meal.
- 73.200 Synthetic iron oxide.
- 73.250 Fruit juice.
- 73.260 Vegetable juice.
- 73.275 Dried algae meal.
- 73.295 Tagetes (Aztec marigold) meal and extract.
- 73.300 Carrot oil.
- 73.315 Corn endosperm oil.
- 73.340 Paprika.
- 73.345 Paprika oleoresin.
- 73.350 Mica-based pearlescent pigments.
- 73.352 Paracoccus pigment.
- 73.355 Phaffia yeast.
- 73.450 Riboflavin.
- 73.500 Saffron.
- 73.575 Titanium dioxide.
- 73.585 Tomato lycopene extract; tomato lycopene concentrate.
- 73.600 Turmeric.
- 73.615 Turmeric oleoresin.

Subpart B—Drugs

- 73.1001 Diluents in color additive mixtures for drug use exempt from certification.
- 73.1010 Alumina (dried aluminum hydroxide).
- 73.1015 Chromium-cobalt-aluminum oxide.
- 73.1025 Ferric ammonium citrate.
- 73.1030 Annatto extract.
- 73.1070 Calcium carbonate.
- 73.1075 Canthaxanthin.
- 73.1085 Caramel.
- 73.1095 β -Carotene.
- 73.1100 Cochineal extract; carmine.
- 73.1125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).
- 73.1150 Dihydroxyacetone.